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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/016,869	01/30/98	BEACH	D 071.10

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EXAMINER	
TUNG, M	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 08/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/016,869	Applicant(s) Beach, et al.
	Examiner Mary B. Tung	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Mar 23, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1, 10, 11, and 58-78* is/are pending in the applicat

Of the above, claim(s) *1 and 10* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *11 and 58-78* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Claims 1-57 were originally presented.

2. Claims 2-9 and 12-57 were cancelled in the amendment filed 10/7/98, Paper No. 7.

3. Claims 58-76 were added in Paper No. 7.

4. Claims 77 and 78 were added in the paper filed 3/23/00, Paper No. 12.

5. Claims 1 and 10 stand non-elected.

6. Claims 11 and 58-78 are under consideration.

In light of the amendment filed in Paper No. 12, only the following rejections remain:

Claim Rejections - 35 U.S.C. § 112

7. The rejection of claims 58-64 under 35 U.S.C. 112, first paragraph, as having a lack of support in the specification or claims as originally filed for the recitation "at least four ankyrin-repeats", is hereby withdrawn in light of the disclosure of said recitation on page 55, line 37.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of *35 U.S.C. § 102* that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the Applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the Applicant for patent.

9. Claims 11, 58-61 and 65-67 and new claims 77 and 78 stand rejected under 35 U.S.C. 102(e) as being anticipated by Skolnick, et al. *(US Patent No. 5,624,819).*

10. The '819 patent teaches an antibody (polyclonal antibody, as recited in claim *65*, col. 14, monoclonal antibody, col. 15, as recited in claim *61*) to a Cdk-binding protein encoded by a 947 bp sequence (for example, SEQ ID NO: 36; see col. 14, lines 28-63 and col. 15, lines 4-45). The identification of the taught MTS protein (p16) as

interacting with Cdk, as recited in claim *11*, is taught in col. 8, line 61 and bridging over to col. 9, line 17 and col. 28, lines 2-34). The '819 patent teaches a 947 bp nucleotide (SEQ ID NO: 36) with a 94.9% sequence identity to SEQ ID NO: 1 of the instant application, a 751 bp sequence (SEQ ID NO: 15) with a 80.9% identity with SEQ ID NO: 3, a 395 bp nucleotide (SEQ ID NO: 25) with 98.5% identity over its entire length with SEQ ID NO: 5 of the instant application. Additionally, the '819 patent teaches a 156 amino acid sequence (SEQ ID NO: 2) with 98.6% identity with SEQ ID NO: 2 (see claim 1), and a 138 amino acid sequence (SEQ ID NO: 16) with 95.7% identity with SEQ ID NO: 4. The polypeptides of the '819 patent would inherently possess most of the same epitopes as the polypeptides disclosed herein, therefore, the antibodies of claims *11, 58, 60, 61, 65 and 67* would be encompassed by the teaching. Additionally, the nucleic acids disclosed in the '819 would inherently encode polypeptides with the same epitopes as disclosed herein and thus, the antibodies of claims *11, 58, 59, 61, 65 and 66* would be encompassed by the teaching. Therefore, the reference teachings anticipate the claimed invention.

Applicant submit that their earliest filing support of the presently claimed invention may precede the disclosure by Skolnick et al. and disqualify Skolnick et al. as prior art.

Applicant's assertion that they cannot discern from the record which priority date disclosure constitutes the enabling disclosure of the prior art is acknowledged.

The priority documents of Skolnick were not available to the Examiner at this time.

In the absence of objective evidence to the contrary; for examination purposes, the effective 102(e) priority date of Skolnick et al. is 5/18/94. Applicant is invited to provide documentary support (e.g. copies of Applicant's priority documents) to support the earliest priority date of the instant claims. Applicant is reminded that such priority relies upon 35 U.S.C. 112, first paragraph, enablement and written description.

11. The rejection of claim 65 under 35 U.S.C. 102(b) as being anticipated by Booher, et al. *(Cell 58:485-497, 1989)* is hereby withdrawn in light of the amendment to the claim.

Claim Rejections - 35 U.S.C. § 103

12. The following is a quotation of *35 U.S.C. § 103* which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 11 and 58-76 and new claims 77 and 78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Skolnick, et al. *(US Patent No. 5,624,819)*.

15. The '819 patent has been discussed supra. The '819 patent does not teach a kit comprising antibodies to the recited CCR protein. However, one of ordinary skill in the art would recognize that reagents in kit form, as recited in claims *68-76*, would be required to perform the screening assays taught in the '819 patent (see col. 28) using current clinical requirements for standardized reagents. Additionally, one of ordinary skill in the art would recognize the advantage of using antibodies in Fab or F(antibody')$_2$, form, as recited in claims *62 and 63*, for use in antibody staining techniques, wherein the absence of an Fc region reduces background, particularly if using FACS analysis. Also having a detectable label on the claimed antibody, as claimed in claim *64*, would also reduce background if used in a direct antibody-binding detection procedure. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants repeated their arguments concerning Skolnick, as discussed *supra*.

Applicant submit that their earliest filing support of the presently claimed invention may precede the disclosure by Skolnick et al. and disqualify Skolnick et al. as prior art.

Applicant's assertion that they cannot discern from the record which priority date disclosure constitutes the enabling disclosure of the prior art is acknowledged.

The priority documents of Skolnick were not available to the Examiner at this time.

In the absence of objective evidence to the contrary; for examination purposes, the effective 102(e) priority date of Skolnick et al. is 5/18/94. Applicant is invited to provide documentary support (e.g. copies of Applicant's priority documents) to support the earliest priority date of the instant claims. Applicant is reminded that such priority relies upon 35 U.S.C. 112, first paragraph, enablement and written description.

The following new grounds for rejection are necessitated by amendment:

Claim Rejections - 35 U.S.C. § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claims 65, 77 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

18. Claims 65, 77 and 78 recite a preparation of polyclonal antibodies, wherein a CCR protein is at least 80%, 90% or 95% identical to SEQ ID NOS: 2, 4 or 6, respectively. The specification fails to disclose any common essential features that an amino acid sequence having 80 %, 90% or 95 % sequence identity with SEQ ID NOS: 2, 4 or 6 would possess. The essential element of the invention is the characteristics of the CCR polypeptide, however, the Applicants have not provided disclosure in the specification as to the structure and function relationship that is essential to the claimed antibody to the CCR. The specification and claims do not indicate what distinguishing attributes are shared by the members of the claimed genus. The scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and the claims do not provide any guidance as to what changes should be made or what structural features that could distinguish compounds in the genus from others in the genus are missing from the disclosure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variable, SEQ ID NOS: 2, 4, or 6 alone is insufficient to describe the genus or the claimed methods. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

19. Applicant is directed to the Revised Interim Written Description Guidelines, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999. In keeping with the revised written description guidelines and corresponding training materials (available on the PTO Website), the claimed invention lacks adequate written description in the specification.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

21. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. This application contains claims 1 and 10, drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

23. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm, and on alternating Mondays. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Serial Number: 09/016,869
Art Unit 1644

August 11, 2000
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640

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ART UNIT ~~182~~ 1644